

## GENETIC TESTING AND DISCRIMINATION: HOW PRIVATE IS YOUR INFORMATION?

The Honorable Louise McIntosh Slaughter\*

Twelve years ago, the world was electrified by the discovery of the first genetic mutation linked to breast cancer. In this short decade, many more genetic links to disease have been identified, dozens of genetic tests have become commercially available, and genetic technology has become firmly embedded in the practice of medicine.

Today, there are over 15,500 recognized genetic disorders. Thirteen million Americans are impacted by these disorders; however, each person possesses some potentially lethal genes.<sup>1</sup> The influence of genetics on our society is profound. For example, up to thirty percent of infant deaths are associated with known genetic disorders, fifteen percent of cancers have an identifiable genetic hereditary component, and ten percent of chronic diseases such as heart disease and diabetes are known to have a strong genetic component.<sup>2</sup> While most lethal genetic mutations never manifest themselves, they may have serious implications for children of carriers.

As technology has raced ahead, ethical, legal, and social challenges have presented themselves. We are now faced with critical questions about how we, as a nation, will allow genetic information to be handled and used. Almost ten years ago, I introduced the first legislation in Congress to ban genetic discrimination in health insurance. I considered the bill to be a simple, straightforward, non-controversial proposal that would allow social policy to keep pace with science. I could hardly have imagined that six years would pass before the House held the first hearing on the issue, and far more than that without any meaningful action at all. Congress now stands at a crossroads. We can pass legislation that will protect genetic information from employer and insurance discrimination and thereby encourage Americans to take advantage of genetic testing to prevent and prepare for potential diseases, or we can

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1. MICHELE SCHOONMAKER & ERIN D. WILLIAMS, CONG. RESEARCH SERV., CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS: GENETIC TESTING: SCIENTIFIC BACKGROUND AND NONDISCRIMINATION LEGISLATION 3-4 (updated March 21, 2005).

2. *Id.*

continue to stand idly by at the expense of future scientific breakthroughs and American lives.

#### GENETIC TESTING: BENEFITS AND CHALLENGES

Initiated by Congress in 1991, the Human Genome Project was a collaborative effort by the Department of Health and Human Services and the Department of Energy to decode the human genetic sequence. The first phase of the project was successfully completed in April 2003, when scientists finished sequencing the human genome. Phase II of the project began in 2004. Through this next phase, scientists will investigate the clinical applications of the sequenced genome.<sup>3</sup> With the sequencing of the human genetic code, scientists have now identified genetic markers for a variety of chronic health conditions, increasing the potential for early treatment and prevention of numerous diseases. Genetic tests provide information to diagnose and guide treatment decisions or predictive information about the future risk of disease.

The Johns Hopkins University Genetics and Public Policy Center defines genetic testing as “the laboratory analysis of DNA, RNA, or chromosomes. Testing can also involve analysis of proteins and metabolites that are the products of genes.”<sup>4</sup> While there are few cures for genetic diseases, genetic testing does provide individuals information about their risk of developing a disease in the future.<sup>5</sup> However, no one should automatically assume that a person who tests positive for a genetic mutation will necessarily develop a disease. Instead, genetic tests may only suggest that an individual is at risk for developing a disease. In fact, a person with a genetic mutation may remain asymptomatic over his entire life.

Clinical genetic tests are now available. While most are for rare genetic disorders, clinical tests to determine future susceptibility to disease and responses to medication are increasingly coming on the market. Today, nearly 600 laboratories can provide genetic testing for more than 1100 diseases.<sup>6</sup> However, without legal guarantees for job and insurance protections, far too many individuals will forgo tests that could save their lives.

#### GENETIC DISCRIMINATION: IS IT REALLY A PROBLEM?

Genetic issues are insinuating themselves into not only health care decisions, but into many other facets of Americans’ lives. For example, under a

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3. *Id.* at 4.

4. JOHNS HOPKINS UNIVERSITY GENETICS AND PUBLIC POLICY CENTER, REPRODUCTIVE GENETIC TESTING: WHAT AMERICA THINKS 4 (2004).

5. SCHOONMAKER & WILLIAMS, *supra* note 1, at 3.

6. *Id.* at 8, 10.

program called Dor Yeshorim, Hasidic youth take a battery of genetic tests to determine whether they are carriers for any of ten serious genetic disorders. Young men and women who are carriers for a given disorder are discouraged from courting each other, based on the fact that there would be a twenty-five percent chance that their children would be born with a genetic disorder. Throughout the country, advertisements for genetic tests for paternity can be seen in newspapers and on roadside billboards.<sup>7</sup>

No human being has a perfect set of genes. In fact, every one of us is estimated to be genetically predisposed to between five and fifty serious disorders.<sup>8</sup> Every person is therefore a potential victim of genetic discrimination. Fortunately, simply carrying a given genetic mutation does not guarantee that one will fall ill. A genetic flaw simply confers a level of risk upon the carrier that a condition may or may not manifest itself in as long as thirty to forty years. With our knowledge of genetics still in its infancy, scientists have only a rudimentary understanding of how much additional risk a genetic mutation may carry. We have virtually no understanding of how environmental factors, such as diet, smoking, and exposure to chemicals or radiation, interact with genetics to cause disease. To examine the impact of environmental chemical pollutants on health, I have introduced the Environmental Health Research Act to each Congress since 2000. However, given that scientists cannot accurately predict when or whether a carrier will develop a genetic disorder and what environmental factors may have causal relations with particular diseases, it seems imprudent to allow genetic information to be used by health insurers or employers to discriminate.

Some have called the legislation in Congress “a solution in search of a problem” and suggest that genetic discrimination is rare, if it happens at all. Unfortunately, genetic discrimination has already occurred. In 2000, the Burlington Northern Santa Fe Railroad performed genetic tests on employees without their knowledge or consent. The workers involved had applied for workers compensation, and the tests were conducted to undermine their claims. One worker had refused to submit a blood sample for genetic testing and consequently was threatened with termination. Burlington Northern Santa Fe Railroad settled these cases in April 2001 for \$2.2 million.<sup>9</sup>

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7. *Genetic Non-Discrimination: Examining the Implications for Workers and Employers: Hearing Before the Subcomm. on Employer-Employee Relations of the House Education and the Workforce Comm.*, 108th Cong. 87 (2004) (statement of Rep. Louise M. Slaughter, Member of Congress).

8. *Id.*

9. SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, OFFICE OF BIOTECHNOLOGY ACTIVITIES: NAT'L INST. OF HEALTH, A ROADMAP FOR THE INTEGRATION OF GENETICS AND GENOMICS IN SOCIETY: REPORT ON THE STUDY PRIORITIES OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY 20 (2004), available at <http://www4.od.nih.gov/oba/sacghs/reports/reports.html> [hereinafter A ROADMAP FOR THE INTEGRATION OF GENETICS AND GENOMICS IN SOCIETY] ; THE U.S. EQUAL

In 1998, Lawrence Berkeley National Laboratory was found to have been performing tests for syphilis, pregnancy, and sickle cell on employees without their knowledge or consent for years.<sup>10</sup> Throughout the 1970s, many African Americans were denied jobs, educational opportunities, and insurance based on their carrier status for sickle cell anemia, again, despite the fact that a carrier lacked the two copies of a mutation necessary to get sick.<sup>11</sup>

When the Secretary's Advisory Committee on Genetics, Health, and Society met in 2004, many individuals presented personal testimonials of discrimination initiated by an insurance company or employer because of a genetic predisposition. In 2000, Mrs. Jolene Hollar of Arizona was turned down by two life insurance companies because her family had a history of Huntington's disease. Mrs. Hollar herself had not been tested for the gene. One of the companies wrote, "Reconsideration would be available once the testing has been completed and you test negative to this gene."<sup>12</sup> In the case of Ms. Terri Seargent, the repercussions of her genetic tests were more severe. Ms. Seargent was tested and diagnosed with alpha-1 antitrypsin deficiency, which she could control with medication. Shortly following her diagnosis, she lost her job. Without employment, and having a pre-existing condition, she also lost her health, life, and disability insurance. Sadly, Ms. Seargent's case, along with the cases at Burlington Northern Santa Fe Railroad, Lawrence Livermore, and others provide excellent examples of why protections against discrimination are necessary both in the workplace and through insurance companies.<sup>13</sup>

#### GENETIC DISCRIMINATION: RAMIFICATIONS FOR AMERICA'S PUBLIC HEALTH AND SCIENTIFIC RESEARCH

As a consequence of these stories and the public's perceived fear of genetic discrimination, many individuals are deciding against having genetic tests or participating in genetic research, much to the detriment of Americans' public health and the future benefits of scientific research. Others are opting to take genetic tests under an assumed name or pay out-of-pocket in order to learn

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EMPLOYMENT OPPORTUNITY COMM., EEOC SETTLES ADA SUIT AGAINST BNSF FOR GENETIC BIAS (April 18, 2001), at <http://www.eeoc.gov/press/4-18-01.html>; SCHOONMAKER & WILLIAMS, *supra* note 1, at 22.

10. SCHOONMAKER & WILLIAMS, *supra* note 1, at 23.

11. A ROADMAP FOR THE INTEGRATION OF GENETICS AND GENOMICS IN SOCIETY, *supra* note 9, at 20.

12. See SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, OFFICE OF BIOTECHNOLOGY ACTIVITIES: NAT'L INST. OF HEALTH, PUBLIC PERSPECTIVES ON GENETIC DISCRIMINATION: COMMENTS FROM THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY 29, 30 (2004) [hereinafter PUBLIC PERSPECTIVES ON GENETIC DISCRIMINATION], available at [http://www4.od.nih.gov/oba/sacghs/reports/Public\\_Perspectives\\_GenDiscrim.pdf](http://www4.od.nih.gov/oba/sacghs/reports/Public_Perspectives_GenDiscrim.pdf).

13. SCHOONMAKER & WILLIAMS, *supra* note 1, at 21.

valuable information about their potential future health status, so as to start prevention regimens early and still maintain financial solvency. In a letter to the National Institutes of Health, one person described how he and others were using “bogus” names and fake addresses to get genetic testing so that they could properly acquire the necessary insurance without discrimination before becoming symptomatic with a disease.<sup>14</sup>

A study conducted from 2001 to 2003 surveyed 86,859 adults about their willingness to undergo genetic testing. The results, published in June 2005, revealed that forty percent of participants surveyed felt genetic testing was not a good idea for fear that health insurance companies might deny or drop them from their insurance plan.<sup>15</sup> The Genetics and Public Policy Center at Johns Hopkins University has conducted surveys on the public’s views about the privacy of genetic information. In 2002, eighty-five percent of those surveyed did not want employers to have access to their genetic information. By 2004, that number had risen to ninety-two percent. In 2002, sixty-eight percent of those surveyed said their genetic information should be kept private from health insurers; by 2004, it had increased to eighty percent.<sup>16</sup> Clearly, overwhelming majorities wish to keep this information out of the hands of insurers and employers, who may use it to undermine, rather than advance, an individual’s best interests.

Fears about privacy do not just resonate with the public. Health care professionals are also hesitant to make genetic information available. In one survey of genetic counselors, 108 out of 159 indicated that they would not submit charges for a genetic test to their insurance companies primarily because of the fear of discrimination. Twenty-five percent responded that they would use an alias to obtain a genetic test in order to reduce the risk of discrimination and maximize confidentiality. Moreover, sixty percent indicated that they would not share the information with a colleague because of the need for privacy and fear of job discrimination.<sup>17</sup>

Studies also have shown that Americans are deciding to forgo genetic testing altogether because they fear discrimination, even if early detection of a particular genetic mutation may help avert premature morbidity and mortality. Hereditary nonpolyposis colorectal cancer (HNPCC) provides an instructive example. Six genes have been identified to determine if a person carries a mutation for HNPCC. HNPCC is the most common hereditary form of colon

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14. See PUBLIC PERSPECTIVES ON GENETIC DISCRIMINATION, *supra* note 12, at 27.

15. Mark A. Hall et al., *Concerns in a Primary Care Population About Genetic Discrimination by Insurers*, 7 GENETIC MED. 313 (2005).

16. *Genetic Non-Discrimination: Examining the Implications for Workers and Employers: Hearing Before the Subcomm. on Employer-Employee Relations of the House Education and the Workforce Comm.*, 108th Cong. 10 (2004) (statement of Kathy Hudson, Director of Genetics and Public Policy Center, Johns Hopkins University).

17. SCHOONMAKER ET AL., *supra* note 1, at 25.

cancer, and it is estimated that 380,000 Americans carry an HNPCC mutation. Those with the mutation have a ninety percent lifetime risk of developing one of the cancers associated with HNPCC.<sup>18</sup> Between 1996 and 1999, people identified from families with the HNPCC mutations were asked to participate in a study that offered genetic testing for the mutation. While there were other considerations for not participating in the study, of those who declined genetic testing, thirty-nine percent cited fears about losing health insurance as the reason.<sup>19</sup> The high fear factor led the authors of this study to conclude that without legal protections at the national level to address the public's fear of discrimination, a significant number of Americans will opt not to reap the benefits of advanced screening for cancer that would lead to healthier, longer lives.<sup>20</sup>

Fear of discrimination plays a significant role in decisions about whether to take a genetic test at all, whether to do it under one's own name, whether to pay out-of-pocket or seek insurance reimbursement, and whether to share the information with health care providers, coworkers, or family members. The American people desperately want these protections guaranteed under federal law.

#### GENETIC DISCRIMINATION: WHY CURRENT LAWS ARE INADEQUATE

Some argue that individuals are already protected under existing federal statutes from discrimination based on genetic information. Yet there are no federal laws that comprehensively and specifically provide protections for genetic information in employment and insurance settings. Several existing federal laws touch upon the issues raised by the use of genetic information, including the Health Insurance Portability and Accountability Act (HIPAA), Executive Order 13145, the Americans with Disabilities Act (ADA), and Title VII of the Civil Rights Act of 1963. However, this patchwork of laws and interpretations, untested in the courts, does not adequately address the unique issues surrounding the specific use of genetic information. These laws leave many gaps in protections, which fail to alleviate the public fear of genetic testing, and the ambiguity of current law has resulted in both actual and perceived acts of discrimination leading to an inconsistent application of laws to deal with such grievances.

Recently, the Secretary's Advisory Committee on Genetics, Health, and Society at the Department of Health and Human Services conducted an

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18. Donald W. Hadley et al., *Genetic Counseling and Testing in Families with Hereditary Nonpolyposis Colorectal Cancer*, 163 ARCHIVES INTERNAL MED. 573, 574 (2003).

19. *Id.* at 579.

20. *Id.* at 581-82.

analysis of the ability of current law to protect against genetic discrimination. The analysis found many gaps, and the Advisory Committee concluded that “current law does not adequately protect against discrimination based on genetic predisposition.”<sup>21</sup> After the release of its report, the Advisory Committee sent a letter to Secretary Michael Leavitt, urging him to exert influence to bring about the enactment of federal legislation.<sup>22</sup> At the June 2005 Secretary’s Advisory Committee on Genetics, Health, and Society meeting, Agnes Masny, Chair of the Genetic Discrimination Task Force, again pointed out that current laws and court decisions have left substantial gaps in coverage.<sup>23</sup> Consequently, they have failed to provide the necessary safeguards to protect genetic information.

Recognizing the importance of instituting legislative protections against genetic discrimination, thirty-two states have enacted genetic anti-discrimination provisions in employment laws, and forty-three states have passed laws pertaining to the use of genetic information in health insurance.<sup>24</sup> While it is commendable that states have recognized and acted on the public’s desire for legal protections, these state laws vary widely in application and levels of protection. They also are limited in guaranteeing protection against insurer discrimination because self-insured employee benefit plans are generally exempt from state laws under ERISA. Finally, because state laws are diverse and inconsistent, companies operating in more than one state may experience substantial burdens when trying to comply with various laws.<sup>25</sup> Clearly there is a need for consistent legal protections at the federal level.

The Genetic Information Nondiscrimination Act is necessary for two reasons. First, as biomedical research advances, genetic testing is an increasingly critical tool in the provision of health care. Second, the threat of

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21. ROBERT B. LANMAN, THE SECRETARY’S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY, AN ANALYSIS OF THE ADEQUACY OF CURRENT LAW IN PROTECTING AGAINST GENETIC DISCRIMINATION IN HEALTH INSURANCE AND EMPLOYMENT 23 (May 2005), available at <http://www4.od.nih.gov/oba/SACGHS.htm>.

22. Letter from Reed V. Tuckson, M.D., Secretary’s Advisory Comm. on Genetics, Health, and Society Chair, to Michael O. Leavitt, Secretary of Health and Human Services (May 3, 2005), available at [http://www4.od.nih.gov/oba/sacghs/reports/letter\\_to\\_Sec\\_05\\_03\\_2005.pdf](http://www4.od.nih.gov/oba/sacghs/reports/letter_to_Sec_05_03_2005.pdf).

23. Agnes Masny, Nurse Practitioner and Research Assistant, Fox Chase Cancer Center, SACGHS Efforts on Genetic Discrimination Issue, slide 9, (June 15, 2005), <http://www4.od.nih.gov/oba/SACGHS/meetings/June2005/Masny.pdf>.

24. A ROADMAP FOR THE INTEGRATION OF GENETICS AND GENOMICS IN SOCIETY, *supra* note 9, at 20; E-mail from Michele Schoonmaker, Congressional Research Service, to Rosaline Cohen, et al. (Feb. 16, 2005) (on file with author).

25. Robert B. Lanman, Secretary’s Advisory Comm. on Genetics, Health, and Soc’y, Office of Biotechnology Activities: Nat’l Inst. of Health, An Analysis of the Adequacy of Current Law in Protecting Against Genetic Discrimination in Health Insurance and Employment, slides 1, 16, 18 (2005), <http://www4.od.nih.gov/oba/sacghs/meetings/June2005/Gray.pdf>.

discrimination hinders the use of genetic information in the healthcare setting.

#### THE GENETIC INFORMATION NONDISCRIMINATION ACT

H.R. 1227/S. 306, the Genetic Information Nondiscrimination Act (GINA)<sup>26</sup>, would provide critical protections against genetic discrimination for all Americans. In both the group and individual insurance markets, GINA would prohibit health insurance companies from using genetic information, including information about genetic services, to deny insurance coverage or to adjust premium rates paid by the individual or the group to which the individual belongs. GINA would also bar a health plan professional from requesting or requiring an individual or a family member to undergo genetic testing. Additionally, the bill would prohibit a health care professional from requiring that an individual undergo a genetic test. However, a health professional would not be prohibited from recommending or requesting that a patient take a genetic test. The bill would not prohibit a health professional employed by or affiliated with a health plan from informing an individual about the availability of a genetic test, if such a test is part of a bona fide wellness program.

Health insurers are most likely to use genetic information for discriminatory purposes prior to a person's enrollment. This is the time when insurance companies decide whether to offer a person coverage and at what price. To prevent insurance companies from factoring genetic information into these decisions, GINA would prohibit insurance companies from requesting, requiring or purchasing genetic information about an individual prior to that individual's enrollment. Finally, recognizing that incidental collection of genetic information may occur, GINA would not penalize companies that inadvertently receive genetic information as long as the entities do not use the information to discriminate against an individual.

In addition to offering protections against discrimination by health insurance companies, GINA would bar public and private sector employers, employment agencies, labor organizations, and joint labor-management training programs from making employment-related decisions based on genetic information of applicants and employees. This legislation would make it unlawful to refuse to hire or to discharge employees because of genetic information. Unions also would be barred from making membership decisions based on genetic information, and both unions and employers could not make job referrals based on this information. Individuals would be allowed to address employer violations according to the remedies and procedures allowed under

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26. Available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_bills&docid=f:h1227ih.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:h1227ih.txt.pdf); [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_bills&docid=f:s306es.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s306es.txt.pdf).

current law.

GINA provides protections against discrimination by both insurers and employers, because providing only partial protection against genetic discrimination will still deter people from genetic testing. As evidenced by Ms. Seargent's and others' cases, what good is ensuring that insurers cannot discriminate if people can lose their jobs and consequently their insurance coverage over genetic testing? It is critical that the protections be extended to cover both insurers and employers.

#### GINA: POLITICS AND PLAYERS

In order to understand why GINA has not been enacted into federal law to date, it is necessary to understand the legislative process. Once a bill is introduced in either the House or Senate, it is referred to a committee, which has jurisdiction over the bill. The legislation may be referred to a number of committees that may share jurisdiction over issues or may have exclusive jurisdiction over different components of the bill. Typically a committee will hold a hearing on a bill before it schedules a mark-up. Scheduling a mark-up of a bill is subject to the discretion of the committee chairman. During a mark-up, members of Congress that serve on the committee considering the bill can offer amendments. Once the bill is passed in committee, it can be taken up by the whole House of Representatives for consideration. When a bill passes the House of Representatives, it is then referred to the Senate for consideration, and vice versa if the bill originates in the Senate. The Senate will follow a similar process of referring a bill to committee. Upon passage in the committee, it can be brought before the Senate for consideration.

If a bill passes both the House of Representatives and the Senate, but it is not an identical version when it passes each chamber, conferees from both chambers are appointed to rectify any differences between the two versions of the bill. When conferees have come to an agreement on an identical version, both the House of Representatives and Senate have to vote once again on the conferenced version of the bill. Upon passage by both chambers, the bill is then ready for the President to sign into law.

#### The U.S. Senate

During both the 108th and the current Congress, the Senate passed legislation to protect individuals from genetic discrimination. Senators Olympia Snowe, Edward Kennedy, and many others have championed this bill in the Senate, and the bill has received strong backing from Senate Majority

Leader Bill Frist.<sup>27</sup> In October 2003, the Senate passed this bill by a unanimous vote of ninety-five to zero. Less than two months after the 109th Congress was sworn in, on February 17, 2005, the Senate again passed its bill, S.306, by a vote of ninety-eight to zero.

#### The U.S. House of Representatives

The House of Representatives has not acted on GINA in the 109th Congress. Ten years ago, I introduced the first genetics information nondiscrimination act, and on March 10, 2005, the bill was introduced yet again. It has the support of 166 bipartisan co-sponsors. This bill has been referred to three House committees: the Education and Workforce Committee, the Energy and Commerce Committee, and the Ways and Means Committee.

Last Congress, Chairman John Boehner of the Education and Workforce Committee held a hearing on the issue of genetic discrimination. However, in this Congress, the chairman has not yet scheduled any action on H.R. 1227. Similarly, Energy and Commerce Committee Chairman Joe Barton has not announced any committee action on this bill. Since the bill has never been reported out of committee, it has not been voted on by the House of Representatives.

Due to inaction by these committees, some supporters of H.R. 1227 have suggested splitting the bill into two separate pieces of legislation, one that would provide employer discrimination protections, and another that would provide protections against insurers. Any legislation that does not provide comprehensive protection against discrimination from both insurers and employers is essentially providing false protection. More than 61.8% of Americans get their insurance through their employers.<sup>28</sup> Without job security, guarantees of insurance protections are meaningless. If a person is protected from insurers, but not her employer, she could be fired and lose her insurance coverage anyway. Strong, comprehensive legislation is needed to truly alleviate the public's fear about genetic information discrimination.

#### The Bush Administration

The Bush Administration has come out strongly in support of GINA and has issued a Statement of Administration Policy (SAP) to this effect. In this statement, the President acknowledged that "the potential misuse of [genetic]

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27. *Genetic Discrimination Bill Clears Senate; House in No Hurry to Act*, NATIONAL JOURNAL'S CONGRESSDAILY, Oct. 15, 2003 [hereinafter *CongressDaily*].

28. CHRIS L. PETERSON, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, HEALTH INSURANCE COVERAGE: CHARACTERISTICS OF THE INSURED AND UNINSURED POPULATIONS IN 2003 2 (2004).

information raises serious moral and legal issues.” To address concerns about unwarranted use of genetic information, the President pledged to work with Congress on passage of this legislation.<sup>29</sup>

While the White House has come out in favor of the legislation, the National Institutes of Health have also played a key role in advancing protections for genetic information. Dr. Francis S. Collins, director of the National Human Genome Research Institute at the National Institute of Health, has been urging Congress to pass this legislation since 1995.<sup>30</sup> In a 2003 editorial in *Science*, Dr. Collins wrote, “[the] House needs to approve [GINA] as soon as possible.”<sup>31</sup> In this same editorial, Dr. Collins expressed the sentiment felt widely throughout the medical and scientific communities that genetic discrimination will “slow the pace of the scientific discovery that will yield crucial medical advances. . . . [M]any people have already refused to participate in genetic research for fear of genetic discrimination.”<sup>32</sup> Dr. Collins argues that GINA is an “outstanding effort that successfully addresses the myriad concerns of the biomedical research and health communities.” The editorial concludes with the compelling claim that without passage of this much-needed legislation, Americans will not be able to “fully reap the rewards of the investment already made in human genome research.”<sup>33</sup>

Recently, the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) asked Health and Human Services Secretary Michael Leavitt to exert influence to pass this bill. In the SACGHS’s May 3, 2005 letter to Secretary Leavitt, the Committee urges the Secretary to “use considerable influence to bring about enactment of federal legislation prohibiting genetic discrimination in health insurance and employment.”<sup>34</sup> SACGHS goes on to argue that it has “gathered key stakeholders’ perspectives on this issue,” following up with, “what we have learned through these discussions obligates us to request your intervention on behalf of the public.”<sup>35</sup> The letter goes on to say that there is a lack of specific federal legal protections against genetic discrimination. Finally, the letter raises the concern that widespread public healthcare decisions are being made based on fear rather than best medical

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29. Executive Office of the President, Office of Management and Budget, Statement of Administration Policy. S. 306 – Genetic Information Nondiscrimination Act of 2005 (February 16, 2005), *available at* <http://www.whitehouse.gov/omb/legislative/sap/109-1/s306sap-s.pdf>.

30. CongressDaily, *supra* note 27.

31. Francis S. Collins & James D. Watson, Genetic Discrimination: Time to Act, 302 *SCIENCE* 745 (2003).

32. *Id.*

33. *Id.*

34. Tuckson, *supra* note 22.

35. *Id.*

practices.<sup>36</sup>

### Supporters

All together, there are nearly 300 organizations that support passage of GINA. The Coalition for Genetic Fairness<sup>37</sup> consists of 141 organizations. Its mission is to promote legal protections for genetic information, and it has been outspoken in its support for GINA. In addition to the 141 organizations comprising the Coalition for Genetic Fairness, GINA is supported by the Personalized Medicine Coalition, the American Society of Human Genetics, GeneCare Medical Genetics Center, and the American Osteopathic Association. A dozen industry groups, including Genzyme Genetics and Millennium Pharmaceuticals, Inc. also support passage of GINA.

### Opponents

The Genetic Information Nondiscrimination in Employment (GINE) Coalition has led the opposition to this bill. On the Coalition's steering committee are the U.S. Chamber of Commerce, the Society for Human Resource Management, the National Association of Manufacturers (NAM), HR Policy Association, and the College and University Professional Association for Human Resources. They oppose the bill on several grounds and argue that new federal legislation is not needed. The powerful U.S. Chamber of Commerce and NAM have been especially outspoken against the bill.

### GINA: REFUTING THE OPPOSITION

Time and again, supporters of stronger legal protections have refuted the opposition's contentions that such legislation is not necessary. While opponents argue that there is no evidence that employers or insurers are engaging in discrimination based on genetic makeup, several cases have emerged where employers have indeed engaged in genetic discrimination or at least attempted to do so. Congress should not wait to act until hundreds or thousands of people have experienced genetic discrimination. Today, the opportunities for genetic discrimination are limited precisely because people are not taking tests for fear that this information will be used against them. By doing so, however, they are denying themselves valuable information that they could use to make important healthcare decisions.

Opponents of GINA also contend that genetic information can be useful in

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36. *Id.*

37. Coalition for Genetic Fairness members, <http://www.geneticfairness.org/members.html>.

making some employment decisions. For example, they suggest, a health condition likely to cause seizures could properly be considered a threat to others if the employee were a bus driver or an airline pilot. However, scientists and geneticists have been unable to identify any existing genetic test that would guarantee that a person would develop a condition that would pose a significant danger to others. A genetic mutation only confers a higher risk of developing a disorder. Moreover, few such conditions develop in adulthood suddenly or without warning. Expecting a human resources professional to interpret a genetic test accurately is about as realistic as asking them to predict the weather for May 2009. The vast majority of genetic tests have no bearing whatsoever on an individual's ability to perform the duties of his or her job today. Employers should not be permitted to deny job opportunities to entire categories of workers on the theory that a person might someday get sick.

Then there are those who argue that it is too difficult for employers to comply with fifty different state laws. They also suggest that if Congress enacts legislation barring employment discrimination based on genetic information, Congress should include a safe harbor providing that employers in compliance with the federal standards cannot be liable under state or local laws banning such discrimination. True, a federal law can provide valuable uniformity, but it does not have to trample states' rights in the process. At present, over thirty states have passed laws dealing with some aspect of genetic discrimination, but they are a patchwork of different definitions, standards, and remedies. A federal "floor" would provide a coherent national statement of policy while allowing states to pass additional protections for their residents if they so choose. This is the same model followed by civil rights laws, the Health Insurance Portability and Accountability Act (HIPAA), and numerous others. Congress has a long history of avoiding state pre-emption whenever possible in deference to states' rights. If a given state wishes to be more explicit or extensive in banning genetic discrimination, it should have that right.

Opponents of GINA have argued that if a genetic discrimination law is passed, it should "sunset," or automatically expire, at a set date. Congress routinely uses its committee oversight and hearing processes to examine whether existing laws need to be updated or changed. A sunset provision could only create a dangerous situation where the law would lapse and genetic discrimination would become legal after a period of being banned. Furthermore, no major law protecting Americans' rights has ever contained a sunset, including the Americans with Disabilities Act, the Civil Rights Act of 1964, and the Health Insurance Portability and Accountability Act. Most importantly, there is no reason why genetic discrimination should be banned only temporarily.

Another concern expressed by the opposition is that this legislation would encourage unnecessary and frivolous lawsuits, thereby inundating an already

overburdened court system with expensive litigation.<sup>38</sup> However, many legal analysts have said that by deferring to current law, remedies remain uncertain and are likely to result in costly litigation.<sup>39</sup> GINA ensures a fair, balanced system of enforcement to discourage frivolous litigation. For example, the bill protects companies from being sued for the inadvertent acquisition of medical history or health information. Additionally, the bill requires claimants to exhaust administrative state and Federal Equal Employment Opportunity Commission procedures before seeking court damages or equitable relief, and places a cap on all compensatory and punitive damages against even the largest firms at \$300,000.

Opponents of this bill will continue to put up roadblocks and argue semantics with the goal of preventing passage of this important legislation. In April 2004, an article in *Congress Daily AM* described the lack of action on this legislation as “a textbook case of obstruction by inertia.”<sup>40</sup> The article also identified the U.S. Chamber of Commerce as the primary interest group lobbying Congress not to take up this bill. However, the facts are clear: discrimination is occurring, the public is not seeking genetic testing for fear of discrimination, and the scientific community is suffering for lack of study participants. Ultimately, the true cost of failing to pass this legislation is the damage to America’s public health.

Businesses that do not yet support this legislation should do so for two key reasons. First, increased use of genetic information in the provision of health care will increase the effectiveness of health care and consequently reduce health care costs for employers over time. Second, the development and utilization of genetic information will result in a maturation of the personalized medicine market, with American companies in the molecular testing market predicted to generate \$4.2 billion in revenues by 2006.<sup>41</sup> Without appropriate protections to encourage providers, the health care community, and the public to embrace genetic testing, the health care arena will be incapable of taking full advantage of the important opportunities resulting from the advancement of genetic information and technology.

#### GENETIC INFORMATION PROTECTION: PROSPECTS FOR THE FUTURE

It is imperative that Congress stop genetic discrimination before it becomes even more widespread. Many support enacting federal legislation to protect

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38. See Letter from R. Bruce Josten, U.S. Chamber of Commerce, to Judd Gregg, U.S. Senator (May 13, 2003), <http://www.uschamber.com/issues/letters/2003/030513dna.htm>.

39. LANMAN, *supra* note 21, at 23.

40. *Genetic Discrimination Bill Stalls In House*, NAT’L JOURNAL’S CONGRESSDAILY, April 20, 2004.

41. E-mail from Michele Schoonmaker, *supra* note 24.

genetic testing. H.R. 1227 has 108 bipartisan cosponsors in the House of Representatives. The Senate passed an identical bill, S. 306, by a vote of ninety-eight to zero in February. The Bush Administration has issued statements of Administration Policy supporting the bill. In early May, the Secretary's Advisory Committee on Genetics, Health, and Society at Health and Human Services called on Secretary Leavitt to exert influence to pass this bill after concluding that there is deep-seated public fear about potential misuse of genetic information by health insurance companies and employers and that current federal legal protections are inadequate. Despite this wide range of bipartisan support by the public, the Congress, and the Administration, the House committees have refused to schedule action on the bill. The House of Representatives has failed to fulfill its duty to consider legislation of great importance to the American people.

With the sequencing of the human genome, scientists have made significant progress in deciphering information likely to benefit the health and wellbeing of people throughout this country. Yet, without adequate protections, fears of genetic discrimination have the potential to stifle valuable scientific research. Congress must be at the forefront of this national debate, deliberating upon and crafting policies that will allow science and health care to realize the full potential of genetic research while prohibiting the abuse of genetic information. The American people have demonstrated that they want their genetic information to be kept private, out of fear that employers or insurers may gain access to this information. The arguments against this legislation are simply delaying tactics. Surely we will not make the American people wait another year before they can take a genetic test with full peace of mind. It is unconscionable that we would allow people to deny themselves valuable health information because they fear discrimination. Congress has an obligation to respond to the public's request.

I have worked ten years to see these protections become law, and I am hopeful that my colleagues in Congress will understand the importance of and need for this legislation before another Congress and another critical opportunity to advance public health has passed us by. For the benefit of future scientific discoveries leading to healthier Americans, we must pass GINA without delay.

